Okedi®

Risperidone prolonged-release suspension for injection 75 mg, 100 mg

Instructions for preparing and administering OKEDI®

This material is intended for healthcare professionals.

UK-OKE-23-11/0011
December 2023

Prescribing Information can be found at the end of this document.

ROVI

Instructions for preparing and administering OKEDI®

Preparation

OKEDI® requires close attention to these step-by-step Instructions to help ensure successful administration.

Use components provided

The components in the kit box are specifically designed for use with OKEDI®.
OKEDI® must be reconstituted with the solvent supplied in the kit box.

Do not substitute ANY components of the kit box

Correct dosing

The entire content of the reconstituted syringe must be administered to ensure intended dose of OKEDI® is delivered.

Okedi®

Risperidone prolonged-release suspension for injection 75 mg, 100 mg

OKEDI® is intended for intramuscular use only after reconstitution

and should NOT be administered intravenously or subcutaneously or by any other route. It should be administered by a healthcare professional.
Administer dose immediately after reconstitution.

Discard the kit if any component is damaged

Do not administer OKEDI® in the event of any foreign particulate matter and/or variation of physical aspect is observed.

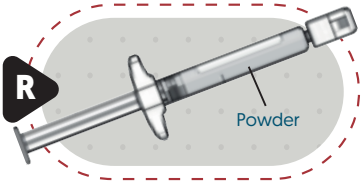
1 **Single use** device.

The kit box of OKEDI® contains:

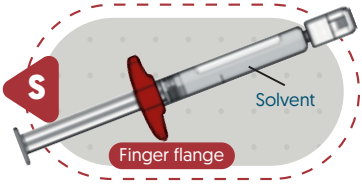
OKEDI® doses are identified by the colour of the **75mg (red)** and **100mg (blue)**.

OKEDI® 75mg
Powder and solvent for prolonged-release suspension for injection
risperidone

POUCH R contains 1 Pre-filled syringe containing risperidone **powder** and a silica gel desiccant sachet.



POUCH S contains 1 Pre-filled syringe containing the **solvent** (liquid) and a silica gel desiccant sachet.



Needles for injection - **each** box kit contains

OKEDI® should be administered by deep using the appropriate sterile needle.

Green Cap - Deltoid: 21G, 1 inch
for deltoid administration

Use this needle for deltoid administration, alternating injections between the two deltoid muscles.

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Risperidone prolonged-release suspension for injection 75 mg, 100 mg

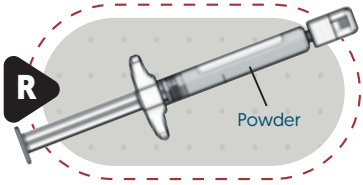
lv finger flange of the solvent pre-filled syringe,

OKEDI® 100 mg

Powder and solvent for prolonged-release suspension for injection

risperidone

POUCH R contains 1 Pre-filled syringe containing risperidone **powder** and a silica gel desiccant sachet.



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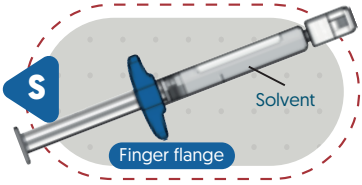


R OKEDI® powder | S Solvent for OKEDI® 75mg | S Solvent for OKEDI® 100mg

2 sterile needles with safety shields.

intramuscular deltoid or gluteal injection

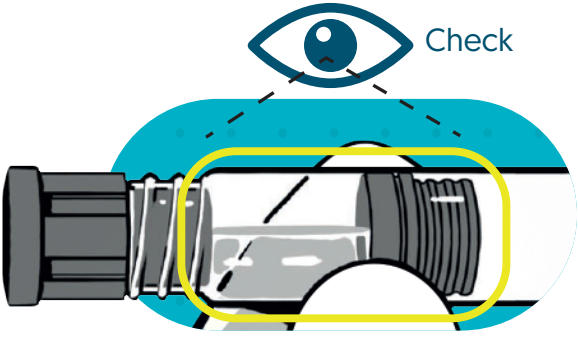
Yellow Cap - Gluteal: 20G, 2 inch
for gluteal administration

Use this needle for gluteal administration, alternating injections between the two gluteal muscles.

Step 1 | Check nature and contents of container

1.1 Inspect solvent syringe

Ensure that solvent syringe content flows normally as a liquid.



If it is frozen or partially frozen, warm it until it is completely thawed*.

*The solvent, DMSO, has a melting point of 18.5°C (64°F) and would solidify at lower room temperatures.

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Risperidone prolonged-release suspension for injection 75 mg, 100 mg

1.2 Dislodge risperidone powder syringe

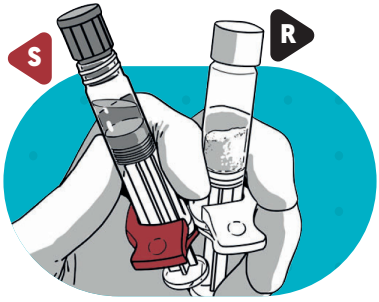
Tap the OKEDI® powder syringe to dislodge potential packed powder near the cap.

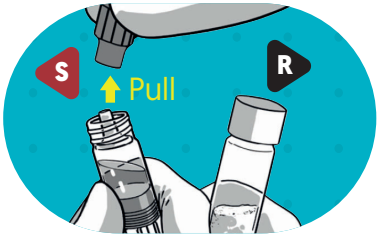
Only the powder syringe contains the active substance risperidone.

Step 2 | Connect the syringes

2.1 Uncap syringes in upright position

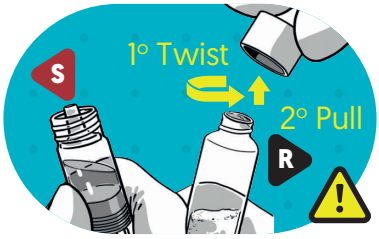
Hold both syringes in upright position to prevent loss of product.





Pull the cap off the solvent syringe.

Twist and pull the powder syringe cap off.



2.2 Connect the syringes

Pick the solvent syringe S that has the coloured finger flange and place it on TOP of the powder syringe R, or slightly angle it when connecting.

TWIST the syringes together until you feel a slight resistance.

Make sure that the powder syringe R is in the upright position to prevent loss of product.

Step 3 | Mix the contents

Important: Stop here and read Step 3 completely before continuing with reconstitution

PUSH VIGOROUSLY
the **solvent** into the **powder syringe**.

DO NOT WAIT
for powder wetting and **QUICKLY** start mixing contents by pushing the plungers **FAST** and alternately for 100 pushes (2 pushes within 1 second, approximately 1 minute).

ENSURE
Sufficient force is applied when mixing to form a uniform suspension. Note **the suspension is viscous** and **you will need to apply force** when pressing on the plunger rods.

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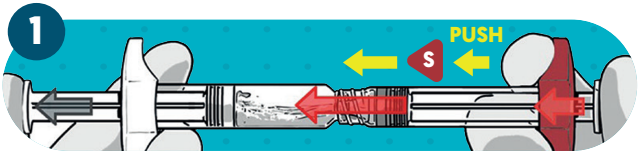
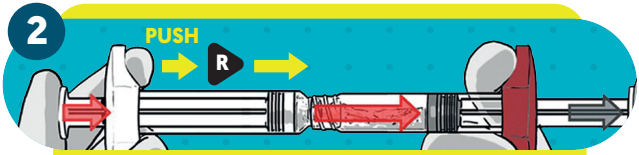
Risperidone prolonged-release suspension for injection 75 mg, 100 mg

Repeat the two step process for at least 100 cycles.





Make sure medicine is passing between both syringes

Push the solvent vigorously into the powder syringe **100 pushes**
(2 pushes / second)

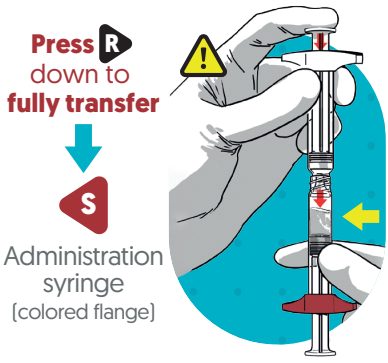
Approx. 1 min.

When the medicine is correctly mixed, the appearance will be a uniform suspension, off white to yellowish colour and thick consistency.

Once reconstituted, proceed inmediately to prepare the injection syringe for administration to avoid loss of homogeneity.

Step 4 | Prepare injection syringe

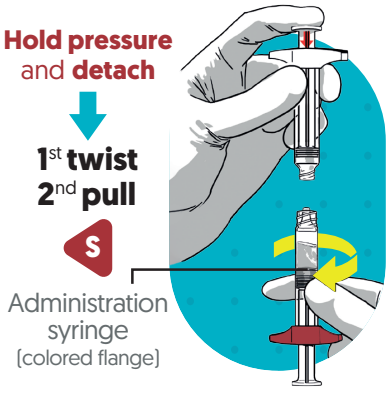
4.1 Transfer medicine



Press down on the plunger to transfer all of the content into the syringe that has the coloured finger flange.

Make sure all the content is transferred.

4.2 Detach syringes



Once the medicine is fully transferred, separate the two syringes by untwisting.

OKEDI® should be administered immediately to avoid loss of homogeneity.

Okedi®

Risperidone prolonged-release suspension for injection 75 mg, 100 mg

4.3 Attach the sterile needle with safety shield - Choose the correct needle

Green Cap - Deltoid: 21G, 1 inch for deltoid administration

Yellow Cap - Gluteal: 20G, 2 inch for gluteal administration

Attach the needle using a clockwise twisting motion. Do not over-tighten.

4.4 Remove excess air

Remove needle cover and push out the excess air (only the big bubbles) from the syringe barrel.

DO NOT expel any drops of medicine.

If medicine is seen at the needle tip, pull back slightly on the plunger to prevent medicine spillage.

Step 5 | Administer and dispose

5.1 Inject medicine

Avoid inadvertent injection into a blood vessel.

Insert the needle fully into the muscle.

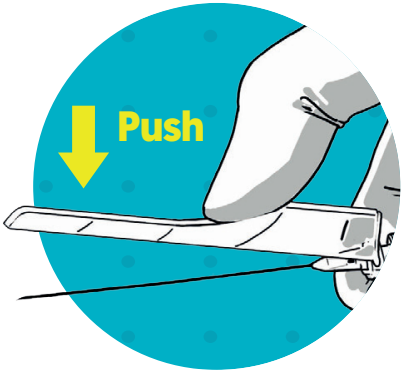
Do not inject by any other route.

OKEDI® should be administered every **28 days** by intramuscular injection.

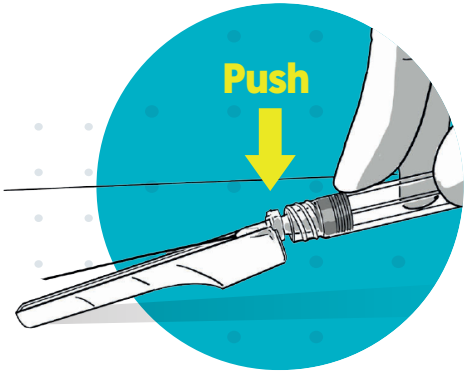
Highly viscous medicine. Make sure to fully inject it.

- **Inject slowly to account for the high viscosity of the suspension.**
- **Wait a few seconds before removing the needle.**

5.2 Dispose medicine



Cover the needle pressing on the needle guard using a finger or a flat surface and dispose immediately in a secure sharps disposal container.



How do I store OKEDI®?

Keep this medicine out of the sight and reach of children.

Store below 30°C

Store in the original package to protect from moisture.
OKEDI® does not require refrigeration.

Do not use this medicine after the expiry date

stated on the carton, aluminium pouches or kit box after (EXP). The expiry date refers to the last day of that month.

Discard the kit if any component is damaged

In the event of any foreign particulate matter and/or variation of physical aspect is observed, do not administer **OKEDI®**.

Okedi®

Risperidone prolonged-release suspension for injection 75 mg, 100 mg

For any information about this medicine, please contact the **local representative** of the Marketing Authorisation Holder

ROVI Biotech Limited
Davis House 4th Floor Suite 425
Robert Street Croydon CR0 1QQ - UK
Tel: + 44 (0) 203 642 06 77
uk-medicalinformation@rovi.com

OKEDI® 75 mg and 100 mg powder and solvent for prolonged release suspension for intramuscular (IM) injection

Prescribing information

Please refer to Summary of Product Characteristics (SmPC) before prescribing

Presentation: Each pre-filled syringe contains 75 mg or 100 mg risperidone **Indication:** OKEDI is indicated for the treatment of schizophrenia in adults for whom tolerability and effectiveness to risperidone have been established. **Posology and Method of Administration:** OKEDI should be administered by a qualified healthcare provider and ***initiated according to the patient's clinical context - see SmPC for detailed guidance.*** Administer OKEDI every 28 days by IM deltoid or gluteal injection. For full details on the preparation, reconstitution, and administration, see *'Instructions for healthcare professionals'* provided in the package leaflet. A maintenance dose of OKEDI 75 mg every 28 days is generally recommended. Some patients may benefit from OKEDI 100 mg every 28 days according to clinical response and tolerability. Neither a loading dose nor supplemental oral risperidone is recommended. **Elderly:** safety and efficacy of OKEDI for patients > 65 years have not been established. **Renal impairment: Mild** (creatinine clearance 60 to 89 mL/min) no dose adjustment required. **Moderate or severe** (creatinine clearance <60mL/min) not recommended. **Hepatic impairment:** use with caution. **CONTRAINDICATIONS:** Hypersensitivity to risperidone or any excipients. **SPECIAL WARNINGS & PRECAUTIONS:** Establish tolerability to oral risperidone prior to OKEDI. Rarely, anaphylactic reactions are reported in patients previously tolerating oral risperidone. If this occurs with OKEDI, discontinue treatment, initiate general supportive measures and monitor until resolved. Do not use in elderly patients with dementia. Caution in cerebrovascular disease, hypotension, cardiovascular disease (including family history of, or known QT prolongation), Parkinson's Disease, Lewy body dementia, seizures, and prolactin-dependent tumours. Monitoring of white blood cell count (WBC) may be needed. Discontinue OKEDI if a clinically significant decline in WBC occurs without other cause. If tardive dyskinesia occurs,

consider discontinuation of all antipsychotics. Caution required in patients receiving concomitant psychostimulants (e.g., methylphenidate) and risperidone. Gradual withdrawal of psychostimulant recommended. Discontinue OKEDI if neuroleptic malignant syndrome occurs. Discontinue OKEDI if Stevens-Johnson syndrome/toxic epidermal necrolysis occurs. Weight gain is common. Monitor patients with, or at risk, of diabetes. Patients with prolonged priapism should seek urgent medical care. Body temperature dysregulation may occur. An antiemetic effect may mask signs and symptoms of other conditions including overdoses. Identify risk factors for venous thromboembolism and take preventative measures. Intraoperative floppy iris syndrome may increase cataract surgery complications. **Interactions with other medicinal products:** No interaction studies have been performed with OKEDI. See SmPC for extensive interaction data based on oral risperidone studies. **Pregnancy and breast feeding:** Should not be used during pregnancy unless clearly necessary. A risk to the breastfed child cannot be excluded. **Undesirable effects:** The most frequent adverse drug reactions reported in an OKEDI phase 3 trial were blood prolactin increased (11.7%), hyperprolactinaemia (7.2%), akathisia (5.5%), headache (4.8%), somnolence (4.1%), weight increased (3.8%), injection site pain (3.1%) and dizziness (3.1%). **Refer to the SmPC for other adverse reactions reported for risperidone from clinical trials and post marketing experience with risperidone medicinal products.**

Legal Category: Prescription Only Medicine (POM).

Presentation and Basic NHS cost: OKEDI 75 mg pack containing one pre-filled syringe - £222.64 OKEDI 100 mg pack containing one pre-filled syringe - £285.52.

Marketing Authorisation (MA) Numbers: PLGB 15406/0018 (75 mg), PLGB15406/0019 (100 mg) **MA Holder:** Laboratorios Farmacéuticos Rovi, S.A., Julián Camarillo, 35, 28037 Madrid, Spain **Date of Preparation:** November 2023.

UK-OKE-23-11/0002

Okedi®

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Adverse events should be reported.
Reporting forms and information can be found at

https://yellowcard.mhra.gov.uk/

or search for MHRA Yellowcard in the Google Play or Apple App Store.
Adverse events should also be reported to

uk-pharmacovigilance@rovi.com

or by telephone +44 (0) 203 642 0677

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